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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,511	12/04/2000	Keith L. Arnold	N1086-071	5552

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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,511

Applicant(s)

ARNOLD ET AL.

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17-19 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-11 and 19 is/are allowed.
- 6) ☒ Claim(s) 6, 17, 18 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 5) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 6) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This Office action is in response to the Response filed 20 October 2003.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's response.
3. The rejection of the claims under 35 U.S.C. § 112, first paragraph, for enablement as related to the deposit of biological materials is withdrawn. The Examiner has reviewed Applicant's statement¹ on the record and finds that the response filed 17 September 2002, page 12, is sufficient to overcome this rejection.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 6, 17 and 18 remain rejected and claim 24 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2003. Applicant's arguments filed 20 October 2003 have been fully considered but they are not persuasive.

Applicant argues that, as directed to claim 6, numerous different cytoplasmic male sterility genes and systems were patented and that male sterile plants have been fully described (pages 2-3 of the Response). This argument is not found to be fully

persuasive because Applicant does not describe corn inbred line LH246 as male sterile, and the instant claim is not directed to a product by process by which the claimed male sterile plant is made. It is suggested that claim 6 be cancelled and the following claims be submitted that would be allowable and adequately described.

Claim 33 (new) A male sterile corn plant produced by transforming the corn plant of claim 2 with a transgene that confers male sterility.

Claim 34 (new) A method of introducing a desired male sterility trait into maize inbred line LH246 comprising:

(a) crossing LH246 plants grown from LH246 seed, representative seed of which has been deposited under ATCC Accession No. _____, with plants of another maize line that comprise a desired male sterility trait to produce F1 progeny plants;

(b) selecting F1 progeny plants that have the desired male sterility trait to produce selected F1 progeny plants;

(c) crossing the selected progeny plants with the LH246 plant to produce backcross progeny plants;

(d) selecting for backcross progeny plants that have the desired male sterility trait and physiological and morphological characteristics of maize inbred line LH246 listed in the Variety Description Information to produce selected backcross progeny plants; and

(e) repeating steps (c) and (d) three or more times in succession to produce selected fourth or higher backcross progeny plants that comprise the desired male sterility trait and all of the physiological and morphological characteristics of maize

inbred line LH246 listed in the Variety Description Information as determined at the 5% significance level when grown in the same environmental conditions.

Claim 35 (new) A plant produced by the method of claim 34, wherein the plant has the desired male sterility trait and all of the physiological and morphological characteristics of maize inbred line LH246 listed in the Variety Description Information as determined at the 5% significance level when grown in the same environmental conditions.

The limitations at new claims 34 and 35 can be found on pages 10-13 of the specification and in U.S. Patent 5,948,957, which Applicant has incorporated by reference on page 33, 1st paragraph, of the specification. Support can be found in Tables 2A-D of the '957 patent.

At claims 17 and 18, Applicant argues that because corn plant LH246 is an inbred corn plant, all hybrid plants having LH246 as a parent will contain the same genetic contribution from LH246 and thus will be genetically distinct and identifiable from any other corn on this basis. Applicant argues that all of the members of the claimed genus of hybrids have LH246 as one parent, share the structural feature of having the genetic complement of LH246 and that one of skill in the art could thus readily identify the members of the genus (page 4 of the Response). This argument is not found to be persuasive because it is unclear from the instant specification that one of skill in the art can adequately describe the genus of F1 hybrids made by crossing the exemplified LH246 corn inbred line with another corn line, that would be required to practice the method, as broadly claimed. Applicant admits that the breeder can

theoretically generate billions of different genetic combinations via crossing, selfing and mutations, and that the breeder has no direct control at the cellular level (page 3, 1st paragraph of the specification). A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Claim 24 is rejection as lacking adequate written description because it is directed to a method comprising using a plant tissue culture produced from progeny of inbred corn line LH246, said progeny having not been adequately described as outlined in the rejections of claims 17 and 18.

Applicant's arguments as directed to a description of the genus of transformed LH246 plants at page 5, 1st paragraph, of the Response is irrelevant to the instant rejection as none of the rejected claims are directed to transformed LH246 plants.

6. Claims 6, 17 and 18 remain rejected and claim 24 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 16 July 2003. Applicant's arguments filed 20 October 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches how to make and use a male sterile plant from LH246 and that it would not constitute undue trial and error experimentation (pages 5-8 of the Response). The Examiner has addressed these

arguments above. The suggested new claims would obviate the instant rejection as directed to claim 6.

Applicant argues that a plant having LH246 [as one of its parents] is made any time LH246 is crossed to another corn plant and that the only way that claims 17 and 18 could be considered to not be enabled for a corn plant having LH246 as one parent is to assume that LH246 is not fertile (paragraph spanning pages 8-9 of the Response). This argument is not found to be persuasive, because it is Applicant's burden to enable the invention within the full scope of the claims. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.". The art recognizes that not all hybrid corn plants are useful as a crop plant because how two corn plants combine genetically cannot be controlled or predicted by one of skill in the art. Applicant admits that the breeder can theoretically generate billions of different genetic combinations via crossing, selfing and mutations, and that the breeder has no direct control at the cellular level as discussed supra. Hence, it remains the Examiner's opinion that it would have

required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through billions of different genetic combinations resulting from the crossing of the exemplified LH246 corn inbred line with other corn lines to practice the method at claims 17 and 18.

Claims 24 is rejected as lacking enablement for the same reasons given for claims 17 and 18, specifically because it is directed to a method comprising using a plant tissue culture produced from progeny of inbred corn line LH246.

7. Claim 24 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

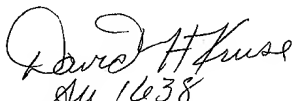
Claim 24 is indefinite because it is unclear where in the method of claim 19 one of skill in the art is to practice "utilizing plant tissue culture methods", or if said claim is directed to an additional method step, hence the metes and bounds of the claimed invention are unclear.

Conclusion

8. This Office action is non-final.
9. Claims 1-5, 7-11 and 19 are allowed.
10. Claims 6, 17, 18 and 24 remain rejected.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539, **(571) 272-0799 after 6 January 2004**. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218, **(571) 272-0804 after 6 January 2004**. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.


David H. Kruse, Ph.D.
17 December 2003